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### REMARKS

Applicants have added new claims 53-55. Claims 1-32 and 53-55 are presently pending in the application.

The Office Action rejected claims 11, 12 and 18 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly describe the subject matter to which Applicants regard as the invention. In particular, the Examiner appeared to query the referenced processes by which these particular claims recite membranes increasing in thickness when brought to their glass transition temperatures. In response, Applicants refer the Examiner to the following passages, taken from the Detailed Description of the presently pending patent application:

For example, when subjected to heat treatment sufficient to bring the membrane to its glass transition temperature, a membrane having a biased molecular orientation may shrink in the direction substantially perpendicular to an axis. As shown in Figure 1a, when the membrane 100 having a biased molecular orientation is subjected to heat treatment, the direction of shrinkage 105 may be substantially perpendicular to the axis 101. In addition, the biased molecular orientation may permit the direction of shrinkage to be controlled or selectively controlled when the membrane is heated. This may be advantageous in situations where specific configurations and sizes are desired for the implantation of the membranes...

...and, subsequently, the membrane is stretched down to a second thickness, wherein the first thickness is greater than the second thickness...

...when the processed and sterilized membrane is subsequently brought to its glass transition temperature, its thickness will or may return back to the first thickness...

...As presently embodied, the shrinkage in the direction perpendicular to the alignment axis or axes will continue until a thickness of the membrane returns from the second thickness to the first thickness...

...Preferably, the thick portion is effective to provide an attachment function to the membrane. In modified embodiments, the thick



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portion may be effective to provide rigidity to at least a portion of the membrane...

...According to a preferred embodiment, however, the attachment means are implemented on the actual thick portions of the thin membrane, although this is not required...

...The glass transition temperature of for example PLLA is about 55° Celsius, while its softening point temperature is above 110° Celsius...

Applicants submit that "thickening" phenomena referenced in claims 11, 12 and 18 may be achieved, for example, by heating a polymer membrane to its glass transition temperature, stretching it from its natural configuration to a contrived configuration wherein its surface area is augmented and its thickness is commensurately attenuated, and, subsequently, allowing the polymer membrane to cool while in the contrived configuration back to a temperature below the glass transition temperature. The polymer membrane will remain in the contrived configuration until it is heated to the glass transition temperature, at which time, to the extent not influenced with external distorting forces, it will return to the original configuration with the greater thickness.

The Office Action rejected claims 1-5, 15-17, and 19-32 as being unpatentable under 35 U.S.C. § 103(a) over Totakura et al. (U.S. Patent No. 5,795,584) and Vyarkaram et al. (U.S. Patent No. 6,333,029) and Tang et al. (U.S. Patent No. 5,412,068), and rejected claims 6-10, 13 and 14 as being unpatentable under 35 U.S.C. § 103(a) over Totakura et al., Vyarkarnam et al. and Tang et al. as applied to claims 1-5, 15-17, and 19-32, and further in view of Lemperle et al. (U.S. Patent No. 6,391,059), Lemperle et al. (U.S. Patent No. 6,280,473), and Mansmann, K. (U.S. Patent No. 6,530,956). Applicants respectively disagrees with these rejections.



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In response, Applicants maintain that the claimed invention is neither anticipated nor obvious in view of any of the prior-art references of record, taken separately or together, in any combination, either in structure or in process. With respect to dependent claims not specifically mentioned, it is submitted that these claims are patentable not only by virtue of their dependencies upon the respective base claims, but also for the totality of features recited therein.

All of the rejections of record rely upon the Examiner's interpretation of Totakura et al. as the base reference and further upon Vyarkaram et al. and Tang et al. These references, taken separately or together, neither disclose nor suggest any of Applicants' claimed combinations.

1. Totakura et al.

The Examiner alleges in the first full paragraph on page 5 of the Office Action that "non-permeability is an essential element, which is also central to [sic] claimed invention." However, Applicants respectfully reply that the presently claimed invention does not have a single "essential" or "central" element, and, instead, is directed to novel combinations of elements. It is noted, for example, that claim 31 does not include a non-porosity limitation, while dependent claim 32 does.

In that same first full paragraph on page 5 of the Office Action, the Examiner alleges that "Totokura et al. teach a viscosity property of 0.9," but does not provide a citation. Applicants request a citation, so that a response to the Examiner's contention may be provided.

Moreover, the same paragraph on page 5 of the Office Action contains an assertion by the Examiner that Example 4 (column 12, lines 45 and 46) of Totokura et al. teach that "the inherent viscosity of this polymer as 06 [sic] to 1.1 dl/g," but Applicants respectfully submit that "this polymer" does not amount to any of Applicants' claimed membranes. Rather, the inherent viscosity referred to in Example 4 appears merely to be a "Polymer IV." The referenced Example



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4 neither discloses nor suggests, by any interpretation, a membrane having Applicants' claimed limitations including an inherent viscosity greater than about 1 g/dL."

Furthermore, the Examiner further alleges in the same paragraph of the Office Action that Totokura et al. discloses ranges that "encompass the ranges disclosed in [sic] subject invention." Applicants find no logic or basis for this statement. In any event, to the extent that Totokura et al. teaches thickness ranges of membranes from 1 cm x 2 to 2 cm x 3 cm, as alleged by the Examiner, Applicants respectfully submit that these ranges are not encompassed by the presently claimed invention. In particular, the range of "0.001 mm to about 0.300 mm" in Applicants' independent claim 1 converts to a range of 0.0001 cm to .03 cm, and the range of "about 0.010 mm to about 0.030 mm" in Applicants' independent claim 25 converts to a range of 0.001 cm to about 0.003 cm. Neither of these claimed ranges are encompassed by the Totokura et al. numbers of 1 cm x 2 to 2 cm x 3 cm.

## 2. Vyarkaram et al.

Clearly, this reference does not appear to be relevant to Applicants' claimed combinations. The Examiner correctly characterizes the reference as not teaching non-porous membranes. However, this reference also fails to disclose a membrane with first and second opposing smooth-surfaces. Nor does the Vyarkaram et al. reference appear to disclose other limitations of Applicants' claimed combinations. The Office Action appears to place value in this reference and rely upon it for disclosing various polymers and combinations of polymers; but the Examiner should note, however, Applicants are not seeking to claim protection for a mere polymer or copolymer formulation in the abstract. Nor are the Applicants seeking to claim protection for every resorbable film in existence. The current claims certainly are not so broad. This reference would appear to provide nothing more than a general indication of the state of the art, with regard to the existence of a few particular polymer formulations, at a time prior to Applicants' invention.



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3. Tang et al.

The Examiner appears to rely on Tang et al. for its statement that "bioresorbable polymers [have been] used in...devices...for decades," but even Applicants' Background section implies this.

For example, the Background section of the current application, characterizes Tokahura et al. as disclosing a non-porous, single layer adhesion film. The Totakura et al. and Tang et al. patents are even described in the Background section of Applicants' parent application as being formed of a bioabsorbable polymer that is copolymerized with a suitable carbonate and a polymeric hydrogel made without crosslinking with urethane chemistry, respectively. These patents involve relatively complex chemical formulas and/or reactions resulting in particular structures to be used as surgical adhesion barriers, which structures do not meet, teach, nor suggest, in any combination with any of the other references of record, the limitations of any of Applicants' claimed combinations.

Applicants wish to reiterate that the claimed combinations of the subject application are not so broad so as to encompass any and all bioresorbable polymer implants, by any means, and rather are directed to particular membranes having particular compositions and constructions. More particularly, the currently claimed membranes comprise smooth, uniform layers of polymer material having predefined viscosity properties and thicknesses, which are neither disclosed, taught, nor even suggested by the prior art of record.

Regarding, in particular, Tang et al., for example, for the most part, the homopolymers and copolymers disclosed in the Tang et al. patent are in the form of fibers or filaments (examples 3, 12-16, 24-28, 40 and 46), powder (example 4), tubes (examples 41-45 and 51) and coatings (examples 52 and 53). In a few cases, copolymer fibers are woven into fabrics (examples 29, 34, 35 and 47). However, weaving inherently produces interstices between



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strands, which would appear to prevent the "fabrics" disclosed by Tang et al. from having first and second substantially smooth opposing surfaces. Out of the 53 examples given in the Tang et al. patent, only 2 (examples 47 and 49) would appear to disclose "membranes", and in both cases, they are asymmetric. The membrane of example 47, for instance, is described as having "one tight surface," while the membrane of example 49 "as a tight, smooth, non-porous side . . . and a highly porous reverse side . . . [with] many pores and channels throughout the bulk of the film. . ." Accordingly, neither of the two membranes in the Tang et al. examples would appear to meet any of Applicants' claimed combinations, including, for example, a limitation that the polymer base material comprise a single layer having first and second substantially smooth sides. Tang et al. provides no suggestion that polymers may be fabricated as membranes having the characteristics, in combination, corresponding to those claimed by Applicants.

The Examiner alleges in the first paragraph on page 7 of the Office Action that column 7 of "Tang et al. teach descriptions of axes...of fibers..." but Applicants' claimed combinations are directed to membranes rather than fibers. In any event, Applicants respectfully submit that this column 7 of Tang et al. does not even appear even to mention an axis, of any kind, whatsoever, much less a membrane of molecular orientation in a polymer membrane that is biased to at least one axis as claimed. Certainly, the relied-upon language of Tang et al. neither discloses nor suggests, by any interpretation, the "axes" as presently recited in Applicants' claimed combinations. Again, even if, hypothetically, it did, such "axes" described in column 7 would relate to fibers, not membranes as presently claimed by Applicants.

The Examiner further contends in the first paragraph on page 7 of the Office Action that "Tang et al. teach a viscosity property of 3.0 dL/g," but Applicants respectfully submit that this viscosity would appear to be that of a powder, which is nowhere disclosed as being used to form a membrane having a viscosity and other characteristics as currently claimed. Applicants claimed combinations are directed to very particular constructions of membranes, as distinguished to broad formulations of polymer powders.



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The Examiner in the same paragraph of the Office Action continues, alleging that "Tank et al. [sic] teach 'shrinking' as disclosed in instant claims 23 and 24 (column 1, lines 50-56). However, Applicants find no such language that relates even remotely to Applicants' claimed shrinkage of the membrane. To the contrary, the cited language would appear to state "These properties include physical and mechanical compatibility with the vessel to which they are connected, suturability, compliancy, ability to withstand pressure and pressure fluctuations, and flexibility. Required properties also include biocompatibility, sterilizability, and low toxicity, allergenicity, and mutagenicity. Still other required properties include durability...." While these are very particular and encompassing properties, none of them would appear to relate to the "shrinking" feature of Applicants currently claimed combinations.

Accordingly, since the Totakura et al., Vyarkaram et al., and Tang et al. et al. references have not been properly interpreted by the Office Action, Applicants submit that the current rejections relying on these references would appear to be without merit.

Regarding the deficiencies set forth above, the Examiner's attention is directed to Section 706.02(j) of the Manual of Patent Examining Procedure (MPEP), which is entitled "Contents of a 35 U.S.C. 103 Rejection" and which is reproduced, with emphasis, below:

35 U.S.C. 103 authorizes a rejection where, to meet the claim, it is necessary to modify a single reference or to combine it with one or more other references. After indicating that the rejection is under 35 U.S.C. 103, the examiner should set forth in the Office action:

- (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,
- (B) the difference or differences in the claim over the applied reference(s),
- (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and
- (D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification.



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To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria. The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). See MPEP § 2144 - § 2144.09 for examples of reasoning supporting obviousness rejections. Where a reference is relied on to support a rejection, whether or not in a minor capacity, that reference should be positively included in the statement of the rejection. See *In re Hoch*, 428 F.2d 1341, 1342 n.3 166 USPQ 406, 407 n. 3 (CCPA 1970).

It is important for an examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply. Furthermore, if an initially rejected application issues as a patent, the rationale behind an earlier rejection may be important in interpreting the scope of the patent claims. Since issued patents are presumed valid ( 35 U.S.C. 282) and constitute a property right ( 35 U.S.C. 261), the written record must be clear as to the basis for the grant. Since patent examiners cannot normally be compelled to testify in legal proceedings regarding their mental processes (see MPEP § 1701.01), it is important that the written record clearly explain the rationale for decisions made during prosecution of the application.

See MPEP § 2141 - § 2144.09 generally for guidance on patentability determinations under 35 U.S.C. 103, including a discussion of the requirements of *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). See MPEP § 2145 for consideration of applicant's rebuttal arguments. See MPEP § 706.02(I) - § 706.02(I)(3) for a discussion of prior art disqualified under 35 U.S.C. 103(c).



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Applicants respectfully submit that the rejection of claims 1-5, 15-17, and 19-32 as being unpatentable under 35 U.S.C. § 103(a) over Totakura et al. (U.S. Patent No. 5,795,584) and Vyarkaram et al. (U.S. Patent No. 6,333,029) and Tang et al. (U.S. Patent No. 5,412,068) would appear to be incomplete. The Office Action appears to assert a few disjointed abstracts and passages from the prior-art references, but does not provide: all of the differences in each of the rejected claims over the applied references, the proposed modifications or applications of each of the applied reference necessary to arrive at each of the claimed combinations, and explanations of why one of ordinary skill in the art at the time the invention was made would have been motivated to make each of the proposed modifications.

Applicants request that the Examiner present a convincing line of reasoning as to why the artisan would have found each of the claimed combinations to have been obvious in light of the teachings of the references. Moreover, each teaching or suggestion to make each claimed combination and the reasonable expectation of success, once provided by the Examiner, must both be found in the prior art and not based on Applicants' disclosure.

Applicants further request that the examiner properly communicate the basis for the rejection of each of the pending claims, clearly discussing the relevance of each of the relied-upon prior-art references and how they interrelate, so that the issues can be identified early and the applicant can be given fair opportunity to reply. As set forth in the above text from the MPEP, it is important that the written record clearly explain the rationale for the Examiner's rejections.

Furthermore, Applicants request that the criteria of Graham v. John Deere be laid-out in each of the rejections along with an application of those criteria for each of the rejections.



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It is further requested that the Office Action provide proper support for its factual assertions. For example, page 8 of the Office Action alleges that "Lemperle et al. (473) does teach membrane thickness ranges which fall within the instant ranges of 1 micron to 300 microns (column 3, line 62; column 6, lines 9 and 57-50)." However, Applicants find no such ranges, and, indeed, no ranges whatsoever, at the cited passages.

As yet another example, that same passage of the Office Action continues, stating that "Lemperle et al. (473) also teach a range which encompasses instant inventions [sic] highest range (column 16, line 9)." However, Applicants find no such range, and, indeed, no ranges whatsoever, in the relied-upon language of Lemperle et al.

As still a further example, that same passage of the Office Action continues, stating that "Lemperle et al. also teach shrinkage of membrane (column 15, line 37)." However, Applicants find no such language that relates even remotely to Applicants' claimed shrinkage of the membrane. To the contrary, the cited language of Lemperle et al. relates to shrinkage of holes in a membrane, which, indeed, would appear to corresponds to an expansion of the membrane surface area, rather than a shrinkage, as parts of the membrane encroach into the holes.

For at least the provided reasons, it is respectfully submitted that the current claims in the subject application patentably distinguish over, and are allowable over, the prior art of record. Reconsideration and withdrawal of the current prior-art rejections is respectfully requested.

On a related topic, the Examiner's attention is directed to claims 54, 65 and 66. In particular, while not agreeing with the above rejections, Applicants would like to thank Examiner Timothy B. Betton for his thorough search and review of the prior-art, his careful consideration and examination of the present application and claims, and his indication by implication that claims 54, 65 and 66 may contain allowable subject matter. More specifically, it would appear that claims 54, 65 and 66 were not rejected on prior art. Accordingly, Applicants have added



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new claims which correspond to these non-rejected claims, so that these new claims ultimately include all of the limitations of these non-rejected claims and the base and intervening claims from which they depend, and thus assert that these new claims are allowable.

In view of the above, Applicants submit that the application is now in condition for allowance, and an early indication of same is requested. The Examiner is invited to contact the undersigned with any questions

Respectfully submitted,



Kenton R. Mullins  
Attorney for Applicants  
Registration No. 36,331

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STOUT, UXA, BUYAN & MULLINS, LLP  
4 Venture, Suite 300  
Irvine, CA 92618  
Tel: 949-450-1750  
Fax: 949-450-1764